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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/170,980	10/13/1998	JENNIFER L. HILLMAN	PF-0195-2 RCE	7498

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	37

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/170,980	HILLMAN ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,18-20 and 27-32* is/are pending in the application.

4a) Of the above claim(s) *27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,18-20 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *36* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1, 18-20, 26 are examined in the instant application.

This application contains claims drawn to an invention nonelected with traverse in Paper No.5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

REJECTION UNDER 35 USC 101, UTILITY

Claims 1, 18-20, 26 remain rejected under 35 USC 101, pertaining to lack of a specific and/or substantial utility remains for reasons already of record in paper No:34.

Applicant asserts that in the interview of May 06, 2003, Applicant had the impression that the Examiner acknowledged that Applicant's invention was the polypeptide comprising the amino acid sequence of kallikrein 11 protein, a serine protease enzyme molecule, and thus the rejection for lack of utility and enablement due to a lack of utility would be withdrawn.

Applicant asserts that the kallikrein 11 protein has 90% sequence identity to SEQ ID NO:1 and thus Applicant's invention includes the kallikrein 11 protein, the sequence of which falls within the language of claim 1.

Applicant's arguments in paper No:35 have been considered but are found not to be persuasive for the following reasons:

It is noted that the Interview Summary of May 06, 2003 was faxed to Applicant on 07/03/03. Another courtesy copy of said Interview Summary is enclosed herewith.

Applicant clearly misunderstood the Examiner. In the interview of May 06, 2003, together with SPE Anthony Caputa, there was no offering by the Examiner that the rejection for lack of utility and enablement due to a lack of utility would be withdrawn. The Examiner and SPE Caputa only raised the question of the enablement of the claimed variants, which encompass kallikrein 11.

It is further noted that claims 1, 18-20, 26 drawn to SEQ ID NO:1, which is not the same as kallikrein 11, has been and is clearly rejected under 35 USC 101, utility, because there is no indication that SEQ ID NO:1 has serine protease activity, for reasons already of record in paper No:34. Briefly, the presence of a signal sequence important for secretion at the amino terminus of SEQ ID NO:1 only shows that SEQ ID NO:1 is a secreted protein. Further, the conserved residues H65, D113, and S206 are not sufficient for conferring serine protease activity, nor do the 10 conserved cysteine residues. SEQ ID NO:1 does not have the consensus sequence of different members of kallikrein family, and the result of a difference in even one amino acid in this important consensus sequence in the critical catalytic triad of different members of kallikrein family is unpredictable, i.e. it could change the properties or activity of the protein, as taught by Lazar et al, Burgess et al, Ohannesian et al, and Assemat et al, all of record.

Further, after review, it is clear that although the claimed 90% variants encompass kallikrein 11, however, Applicant has not disclosed how to make the claimed variants that have serine protease activity. That is, in the specification and the

claims it has not been shown which sequence of SEQ ID NO:1 confers serine protease, such that one can make a variant of SEQ ID NO:1 that has serine protease activity. This same issue has been discussed in the 112, first paragraph rejection, scope, below.

Thus since one of skill in the art would not know how to make the claimed variants, the claimed variants lack specific and substantial utility.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

Claims 1, 18-20, 26 remain rejected under 35 USC 112, first paragraph, pertaining to lack of support for a specific and/or substantial utility remains for reasons already of record in paper No:34.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Claims 1, 18-20, 26 remain rejected under 35 USC 112, first paragraph pertaining to lack of lack of enablement for a naturally occurring amino acid sequence at least 90% identical to SEQ ID NO:1, said polypeptide has serine protease activity, remains for reasons already of record in paper No:34.

Applicant argues that SEQ ID NO:1 has been convincingly demonstrated to be a serine protease in the interview of May 06, 2003. Applicant argues that common attributes of serine proteases include signal sequences important for kallikrein secretion at the amino terminus, the conserved residues H65, D113, and S206 for serine protease activity, and 10 conserved cysteine residues, which are involved in the formation of five disulfide bonds. Applicant asserts that these common attributes

contribute to the function of SEQ ID NO:1 variants as having serine protease activity. Applicant asserts that the specification provides an assay for the determination of HPAK proteolytic activity. Applicant asserts that thus it is routine to obtain variants of the claimed invention.

Applicant further asserts that nature will determine the appropriate amino acid sequences. Applicant asserts that one could identify the relevant variants by for example hybridization and/or PCR techniques well known in the art.

Applicant's arguments in paper No:35 have been considered but are found not to be persuasive for the following reasons:

SEQ ID NO:1 has not been shown to have serine protease activity, for reasons set forth above and of record. The presence of a signal sequences important for secretion at the amino terminus only shows that SEQ ID NO:1 is a secreted protein. Further, the conserved residues H65, D113, and S206 are not sufficient for conferring serine protease activity, nor do the 10 conserved cysteine residues. SEQ ID NO:1 does not have the consensus sequence of different members of kallikrein family, and the result of a difference in even one amino acid in this important consensus sequence in the critical catalytic triad of different members of kallikrein family is unpredictable, i.e. it could change the properties or activity of the protein, as taught by Lazar et al, Burgess et al, Ohannesian et al, and Assemat et al, all of record.

The specification and the claims do not disclose how and what amino acids have been determined by nature to be substituted, deleted or added in the claimed variants. The nature selection process however is not predictable. Thus one would expect a vast

number of unrelated sequences with unknown function, would be obtained by hybridization or PCR techniques.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

September 03, 2003

SUSAN UNGAR, PH.D
PRIMARY EXAMINER